

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.,
Case No. 18-op-45090*

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.,
Case No. 17-op-45004*

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**Reply in Support of Defendants' Motion to Exclude
Opinions Offered by James Rafalski**

INTRODUCTION

Defendants moved to exclude five opinions offered by Plaintiffs' suspicious order monitoring (SOM) expert James Rafalski, because he provided no basis for them. In response, Plaintiffs retracted two of those opinions. Chief among them, Plaintiffs concede that, contrary to his deposition testimony, Rafalski will "**not** offer opinions about the number of orders that were in fact diverted." Resp. at 2 (emphasis in original). Plaintiffs also concede that Rafalski's so-called "key components" of a SOM system are **not** required by DEA regulations. *Id.* at 8, 10-11. Rafalski should be precluded from offering these two opinions at trial.

With respect to the remaining three opinions subject to Defendants' *Daubert* challenge, Plaintiffs still have not pointed to any admissible bases to support them. First, regarding Rafalski's opinion that a registrant must document and retain due diligence records "forever," Rafalski offers no basis other than his own say-so, and the opinion fails to take into account the official, contrary view of DEA. Second, regarding Rafalski's opinion that a distributor must halt **all** shipments to a customer following the flagging of a **single** potentially suspicious order, Plaintiffs attempt to rely on evidence that Rafalski did not disclose in his report, and that fails to support the opinion in any event. Third, regarding his opinion that manufacturers are required to use chargeback and prescription data to monitor suspicious orders, Plaintiffs continue to rely on Rafalski's "personal experience bringing administrative actions against registrants"—experience that DOJ instructed him not to disclose in his *Touhy* authorization letter and that Rafalski refused to testify about. Plaintiffs do not dispute that Rafalski was required to disclose **all** bases for his opinions in his report under Rule 26, or that the Court is required to strike opinions where no basis has been disclosed under Rule 37. The Court should rule that Rafalski may not offer these three challenged opinions at trial, either.

ARGUMENT

Plaintiffs' response brief treats Defendants' motion as though it seeks to exclude Rafalski's testimony in its entirety. It does not. Defendants' motion narrowly targets five of Rafalski's opinions for exclusion, because they lack any basis disclosed in his report:

1. That *every pill* contained in *every order* flagged by Craig McCann's data analysis *was diverted for unlawful use*.
2. That Rafalski's *so-called "key components"* of a SOM and due diligence system, set forth on pages 37 to 40 of his report, *are regulatory requirements*.
3. That suspicious order reports and *due diligence records must be documented and retained "forever."*
4. That the CSA and its implementing regulations require Defendants to *halt all shipments after identifying an initial potentially suspicious order*, unless and until documented due diligence was performed to dispel suspicions on that order.
5. That the law *requires manufacturers to consider prescription and chargeback data* in monitoring suspicious orders.

See Dkt. 1884/1900 ("Br.") at 8, 12.¹ In response, Plaintiffs retracted the first two of these opinions and failed to provide a basis for the other three. All five should be excluded.

I. Rafalski Should Be Precluded From Offering Two Opinions That Plaintiffs Retracted in Their Response Brief.

In response to Defendants' arguments that Rafalski failed to disclose the bases for certain opinions, Plaintiffs retracted two of those opinions. The Court should rule that Rafalski may not offer testimony on those opinions at trial.

First, Plaintiffs have conceded that Rafalski—a DEA Diversion Investigator for thirteen years—is "not expressing an opinion on the number of suspicious orders that were actually diverted." Dkt. 2253/2260 ("Resp.") at 23. According to Plaintiffs, "there was no reason for Mr. Rafalski to determine whether all of the suspicious orders were in fact suspicious and should not

¹ On first reference, citations to motions, responses, expert reports, and deposition transcripts that have been filed on the docket include the docket numbers (both sealed and public versions, respectively).

have been shipped.” *Id.* at 24. Plaintiffs say that it was “simply not necessary” for Rafalski “to review and opine on specific suspicious orders”—much less any diversion—“to assess a Defendant’s SOM program.” *Id.* That misses the point. Setting aside whether Rafalski can critique a SOM system without identifying any suspicious orders or any diversion, he clearly cannot offer an opinion that any number of pills was actually diverted without having conducted such an analysis.

Second, Plaintiffs concede that “DEA regulations do not mandate specific requirements” of SOM systems. *Id.* at 8. Plaintiffs also acknowledge that “Registrants know their business and their customers better than the DEA and hence are best positioned to design the most effective anti-diversion program.” *Id.* at 10. And they concede, “DEA regulations do not specify the exact components of an anti-diversion program,” and “DEA does not mandate that registrants put in place any particular program.” *Id.* at 10-11. Again, setting aside Rafalski’s opinions about what components he *personally prefers* in a SOM system, he should be precluded from testifying that any item in his laundry list of “key components” *is required by law*.²

Plaintiffs have narrowed Rafalski’s opinions in a way that, in part, comports with Defendants’ motion. The Court should hold Plaintiffs to that narrowing, and rule that Rafalski may not surprise Defendants at trial by offering any of the testimony Plaintiffs have retracted.

II. Plaintiffs Failed to Provide a Supportable Basis for Three Remaining Opinions.

Plaintiffs do not dispute that Rule 26 required Rafalski to disclose *all* bases for his opinions in his report, or that Rule 37(c) requires this Court to exclude testimony where an expert has failed to provide disclosures required by Rule 26. *See Ross v. Am. Red Cross*, No.

² Similarly, Plaintiffs fail to even address the fact that Rafalski did not apply his “key components” to any manufacturer’s SOM system, or that he does not know how they would apply. *See Br.* at 4 & n.2. Rafalski must be precluded from offering opinions about the sufficiency of any manufacturer’s SOM system where he did not take the time to learn anything about the manufacturer that might have allowed him to apply his “key components.”

2:09-cv-905, 2012 WL 2090513, at *2 (S.D. Ohio Jan. 26, 2012). Plaintiffs also acknowledge that Rafalski refused to answer questions about his purported reliance on “legal guidance from the DEA,” based on instructions from the DOJ in its *Touhy* letter regarding the scope of his testimony.³ Plaintiffs assert that the same restrictions were imposed on defense experts, Resp. at 9, but ***no defense expert relied on undisclosed DEA guidance to support his or her opinions.*** Rafalski, by contrast, testified that he ***did*** rely on DEA guidance he refused to disclose. Rafalski Tr. 842:1-19 (Dkt. 1969-19/1983-16). Plaintiffs failed to point to any other supportable, disclosed basis for the three remaining opinions subject to Defendants’ *Daubert* challenge.

First, Plaintiffs do not point to any basis for Rafalski’s frankly startling opinion that due diligence records must be retained “forever,” an opinion that was directly contradicted by DEA’s 30(b)(6) witness. *See* Prevoznik 30(b)(6) Tr. 1212:13-19 (Dkt. 1969-14/1983-11) (“Q. And I believe that you indicated that there was not any sort of requirement by the DEA of the maintenance of due diligence files, correct? A. Yes.”). Plaintiffs appear to concede, moreover, that there is no such requirement in DEA regulations. Resp. at 14. Instead, Plaintiffs simply assert that Defendants’ focus on Rafalski’s testimony that diligence records must be “permanently” retained is a “red herring” that “misses the point.” *Id.*

But Rafalski’s conclusion that Defendants performed insufficient due diligence is a “factual assumption,” *id.* at 13, based on his assertion that, because Defendants did not retain due diligence records that they were ***required by law*** to maintain, they did not conduct due diligence as a matter of fact. If there was no such legal requirement, the entire basis for Rafalski’s opinion

³ Plaintiffs suggest that the “limited scope of Mr. Rafalski’s testimony” was due to Defendants’ failure to notify DOJ of his deposition, so that DOJ’s counsel could attend and instruct Rafalski on the proper scope. Resp. at 9 n.9. But DOJ did not attend ***any*** DEA expert depositions, despite the fact that Defendants, at least, notified DOJ of several of its own DEA experts’ deposition dates. More important, Plaintiffs failed to share Rafalski’s *Touhy* letter—which is addressed to Linda Singer, counsel for Plaintiffs—with Defendants until the deposition started on May 13, though the letter is dated a full month earlier. *See* Ex. 1, April 12, 2019 *Touhy* Letter. If the DOJ did not know the date of Rafalski’s deposition, it is because ***Plaintiffs*** failed to share it with them.

disappears. Rafalski might have *liked* to see more records documenting the diligence Defendants performed back to 1996, but he should not be allowed to testify that Defendants were *required* to maintain those decades-old records for any period of time, as there is no basis for that testimony.

Second, in an effort to salvage Rafalski's blanket opinion that all shipments must be halted after an initial flagged order from a customer, Plaintiffs now point to a variety of sources, including DEA's revocation decision in *Southwood Pharmaceuticals*, 72 FR 36487-01, 2007 WL 1886484 (DEA July 3, 2007), and testimony by DEA witness Thomas Prevoznik. *See* Resp. at 15-16. But Rafalski disclosed *none* of the sources cited in Plaintiffs' response brief as a basis for this opinion in his report. *See* Rafalski Rpt., Dkt. 2000-22/1999-21 at 40. In his report, he relied only on his own say-so. *See id.* In any event, these sources do not support the opinion.

In *Southwood*, for example, the distributor knowingly shipped opioids to internet pharmacies that were "dispensing large numbers of prescriptions which were not issued in the course of a legitimate doctor-patient relationship and thus violated Federal law." 72 FR 36487, at 36491. In fact, *Southwood* knew some of its customers' DEA registrations had expired—and, in one case, had been suspended—but continued to ship to them anyway. *See, e.g., id.* at 36488. *Southwood* is an extreme example—of course the distributor should have halted all shipments to customers who did not possess a valid DEA registration or who knowingly filled illegitimate prescriptions. Rafalski points to *nothing* in any Defendant's records that is in any way similar to those circumstances. Indeed, he admits he did not analyze *any* order to determine whether it was actually suspicious or unlawfully diverted. Rafalski Tr. 192:16-18, 489:16-19, 508:1-18 (Dkt. 1969-18/1983-15 & 1969-19/1983-16). Instead, Rafalski admits: "I don't have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge." *Id.* 582:9-19.

Likewise, Prevoznik’s testimony on behalf of DEA does not support a blanket “halt all subsequent shipments” opinion. To the contrary, Prevoznik testified that if a distributor determines that subsequent orders are not suspicious, then it *is* appropriate to ship those orders. Prevoznik Tr. 1236:11-1238:20 (“Q. They can ship those other orders out? A. Yes.”). Plaintiffs do not even argue for a blanket “halt all subsequent shipments” rule in their motion for summary judgment on Defendants’ legal duties under the CSA. *See generally* Dkt. 1910. The opinion is unsupported, and Rafalski should be precluded from testifying about it at trial.

Third, in support of Rafalski’s opinion that all manufacturers are *required by law* to use chargeback and other prescription data to monitor suspicious orders, Plaintiffs point to three irrelevant sub-regulatory materials, and Rafalski’s “personal experience bringing administrative actions against registrants.” Resp. at 8. But Plaintiffs refused to allow Rafalski to testify about that personal experience. Rafalski Tr. 662:21-663:16 (“Q. Have you ever come across a manufacturer’s suspicious order monitoring program that you did think satisfied regulatory requirements? A. I’m not sure I can discuss that with the *Touhy* letter. **Mr. Fuller: Not if it was based on an investigation that you did while an agent.**”) (emphasis added).⁴

Plaintiffs cannot hide behind DOJ’s *Touhy* letter at deposition to prevent disclosure of necessary reliance materials and yet still offer opinions based on those undisclosed materials at trial. “A party should not be allowed to use confidential information as both a shield and a sword.” *Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, Civ. No.

⁴ In his deposition, Rafalski acknowledged that this opinion was not based on the CSA, DEA regulations, or even official DEA guidance. In fact, Rafalski stands alone in holding the opinion that all manufacturers are required by law to use chargeback and other prescription data to monitor suspicious orders. Several DEA witnesses testified that no such legal obligation exists. *See* Wright Tr. 201:24-202:1 (Dkt. 1972-12/1985-24); Ashley Tr. 159:20-161:8 (Dkt. 1956-7/1974-7); Rannazzisi Tr. 110:7-18 (Dkt. 1969-20/1983-17).

07-190-SLR, 2008 WL 3862091, at *1 (D. Del. Aug. 20, 2008). The *Siemens* case is directly on point and supports the exclusion of Rafalski's opinions based on undisclosed DEA guidance.

Plaintiffs assert that "the *Siemens* court did not preclude that expert from testifying; rather it ruled that the expert could not rely on [undisclosed] studies to support his testimony." Resp. at 9. This is just false. The district court held that "Siemens' motion to strike the portions of Dr. McClellan's expert opinion relating to studies performed at [Los Alamos National Laboratory] is granted." *Id.* at *1. The Federal Circuit affirmed that decision on appeal. 637 F.3d 1269, 1286 (Fed. Cir. 2011). Likewise, this Court should grant Defendants' motion to exclude Rafalski's opinions based on undisclosed reliance materials.

CONCLUSION

Plaintiffs have agreed that Rafalski will not offer two of the opinions that Defendants have challenged. To avoid the possibility of any surprise at trial, the Court should rule that he is ***precluded*** from offering those opinions. Plaintiffs failed to provide any supportable basis for the remaining three opinions that Defendants challenged. The Court should preclude Rafalski from offering those opinions as well.

Dated: August 16, 2019

Respectfully submitted,

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⁵ Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction. They are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the Daubert motions for summary judgment to be filed in the MDL Track One cases.

Noramco does not join this motion.

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of August, 2019, a notice of the foregoing has been served via CM/ECF to all counsel of record.

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